Section 5 510(k) Summary

MAR - 6 2014

510(k) Summary

807.92(c)

SPONSOR **807.92(a)(1)**

Company Name:	VentriPoint, Inc.
Company Address	24 Roy Street, #445 Seattle, WA 98109
Telephone:	206-283-0221
Fax:	None
Contact Person:	Jim Bodtke

Summary Preparation Date: 22 January 2014

DEVICE NAME **807.92(a)(2)**

Trade Name:	VentriPoint Medical System IS-1
Common/Usual Name:	Diagnostic Ultrasound Image Analysis System
Classification Name:	Ultrasonic Pulsed Doppler Imaging System

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

510(k) #	*Product*	*Company*
K102017	Acuson SC2000™ Ultrasound System	Siemens Medical Solutions, Inc
K963807	Echo-Scan with Freehand Scanning	TomTec Imaging Systems GmbH

DEVICE DESCRIPTION **807.92(a)(4)**

The VentriPoint Diagnostic System is a client/server platform consisting of the VentriPoint Medical System (client) and VentriPoint Services (server). The VentriPoint Medical System (VMS) is a cart based system consisting of CE Marked off-the-shelf subassemblies which accepts the digital video output from any 2-D ultrasound machine..

A 3-D tracking system is connected to the ultrasound transducer using a custom sleeve. This system provides 3-D spatial coordinates for the 2-D images. After recording the 2-D images and associated 3-D spatial coordinates, a trained medical professional uses the VMS graphical user interface to place a series of points on the 2-D images corresponding to selected anatomical structures. Those points, along with their 3-D spatial coordinates, are sent by secure internet connection to the VentriPoint Services.

The VentriPoint Services use a Knowledge Based Reconstruction expert system to convert those 3-D points into a dense 3-D model of the right ventricle and sends the model back to the VMS system where the results are displayed on the screen. This initial rendering is reviewed for accuracy by the product user. The border contours generated from the previously placed points are displayed and may be adjusted by the user to achieve a precise fit. Improvements are made

by adding, deleting or moving points on the image slices where needed, after which the information is sent by secure internet connection to the VentriPoint Services to be reconstructed. The review and reconstruction process may be repeated until the user is satisfied that the best contour fit has been made.

Once the 3-D model has been approved by credentialed site personnel, quantitative right ventricle measurements are reported. The data produced by VMS is intended to support qualified licensed medical professionals in clinical decision making when used in conjunction with other patient test information.

DEVICE INTENDED USE **807.92(a)(5)**

The VMS system is an adjunct to existing ultrasound imaging systems and is intended to record, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing. The VMS system is used to record a sequence of conventional cardiac 2-D ultrasound images with the transducer position recorded for each image acquired to compute right ventricular volumes and ejection fraction. Specific anatomic landmarks identified by the product user are transmitted by secure internet connection to a VMS server where 3-D assembly of the right ventricle in adult patients with Pulmonary Arterial Hypertension takes place using Knowledge Based Reconstruction (KBR). The results are then returned to the VMS system for display and further consideration or evaluation by the product user.

COMPARISON OF TECHNICAL CHARACTERISTICS **807.92(a)(6)**

Parameters	VentriPoint Medical System	Siemens SC2000	TomTec Echo-Scan
510(k) Number		K102017	K963807
Indications for Use	The VMS system is an adjunct to existing ultrasound imaging systems and is intended to record, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing. The VMS system is used to record a sequence of conventional cardiac 2-D ultrasound images with the transducer position recorded for each image acquired to compute right ventricular volumes and ejection fraction. Specific anatomic landmarks identified by the product user are transmitted by secure internet connection to a	The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transespohageal, Adult Cephalic, Peripheral Vessel, Intraoperative Neurological, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applicatioris. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.	Echo-Scan™ is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional and 4-dimensional (dynamic 3-D) image processing. It is an add-on accessory for existing ultrasound imaging systems, and is intended to control position and movement of ultrasound transducers for the systematic acquisition of 2 dimensional image slices throughout a volume of interest. The Echo-Scan acquires sets of 2D images and stores them digitally in the TomTec standard 3D image file format for subsequent 3D

	VMS server where 3-D assembly of the right ventricle in adult patients with Pulmonary Arterial Hypertension takes place using Knowledge Based Reconstruction (KBR). The results are then returned to the VMS system for display and further consideration or evaluation by the product user.		tomographic reconstruction and surface rendering with either the Echo-Scan or Echo-View. It is intended as a general purpose digital 3D ultrasound image processing tool for cardiology, radiology, neurology, gastroenterology, urology, surgery, obstetrics and gynecology. The TomTec Freehand Scanning Device is intended for acquiring a sequence of conventional 2D ultrasound images with transducer position recorded for each image acquired. The resulting image data set is intended for storage in the TomTec standard 3D image file format for subsequent 3D tomographic image reconstruction.
Freehand scanning device	Yes	Yes	Yes
RV volume measurement	Yes	Yes	Yes
3-D Reconstruction	Knowledge Based Reconstruction database	Knowledge Based Reconstruction database (only Velocity Vector Imaging (VVI) component)	Automated border detection algorithms
Software Based Analysis Tool	Yes	Yes	Yes
UL 60601-1	Yes	Yes	Yes
UL 60601-2	Yes	Yes	unknown
Windows® OS based analysis system	Yes	Yes	Yes
Real-time Video Capture card	Yes	Yes	Yes
External ECG trigger	Yes	Yes	Yes
Pulsed DC 6DOF magnetic tracking	Yes	No	Yes

system			

NONCLINICAL TESTING **807.92(b)(1)**

Performance bench testing of the VentriPoint Medical System (VMS) was completed to verify accuracy of the PAH reconstruction catalog.

Testing of the PAH catalog consisted of a robust series of automated and manual testing to verify reconstruction accuracy.

CLINICAL TESTING **807.92(b)(2)**

A clinical study of 75 consenting adults with Pulmonary Arterial Hypertension was conducted to assess the accuracy of right ventricle (RV) volumes and ejection fraction (EF) obtained with the VMS system. Standard of care cardiac magnetic resonance imaging (MRI) was used for comparison.

Analysis of the patient imaging data was completed by independent imaging core labs. A thorough analysis of the core lab results and sources of variability indicates that the VMS system is an accurate method of measuring RV volume and EF when compared with MRI analyzed using Simpson's method.

CONCLUSION **807.92(b)(3)**

Similarities with the Predicate Devices

The VMS system is substantially equivalent to the predicate devices in the ability to generate 3-D reconstructions of the cardiac right ventricle from a series of 2-D ultrasound images.

Specifically, the VMS system is substantially equivalent to the Siemens Acuson SC2000 in the use of a knowledge based reconstruction database (the SC2000 Velocity Vector Imaging (VVI) component).

The VMS system is substantially equivalent to the TomTec Echo-Scan in technological characteristics that include:

- PC with Microsoft Windows® OS,
- video capture card,
- tracking device, and
- ECG trigger mechanism

The TomTec Echo-Scan and VMS system share the following common traits:

- Allow for 3-D freehand ultrasound scanning,
- Employs an off-the-shelf, strategically positioned, electromagnetic field generator along with a field disturbance sensor firmly attached to the ultrasound transducer in order to enable high precision positional information for each scan plane, and
- As with the VMS product, the TomTec Echo-Scan enables a 3-D reconstruction of cardiac chambers using 2-D ultrasound images and precision location of all selected data points in space to accomplish the intended clinical use.

Difference with the Predicate Devices
The difference between the VMS system and the TomTec Echo-Scan is how the 3-D Reconstruction takes place. The VMS system uses a Knowledge Based Reconstruction database as does the Siemens Acuson SC2000 while the TomTec Echo-Scan uses Automated Border Detection Algorithms.

Safety and effectiveness
The VMS system is a non-invasive, non-significant risk technology. No adverse events were reported during the clinical trial. Effectiveness was assessed through bench and clinical performance testing using a standard of care method as a comparator. The VMS system introduces no new questions concerning safety or effectiveness and is therefore substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 6, 2014

Ventripoint, Inc.
% Mr. Jim Bodtke
V.P. of Clinical Affairs
24 Roy Street, #445
SEATTLE WA 98109

Re: K140153
Trade/Device Name: Ventripoint Medical System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: II
Product Code: IYN
Dated: January 22, 2014
Received: January 22, 2014

Dear Mr. Bodtke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Section 4 Indications for Use Statement

Indications for Use

510(k) Number (if known): k140153

Device Name: VentriPoint Medical System

Indications for Use:

The VMS system is an adjunct to existing ultrasound imaging systems and is intended to record, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing. The VMS system is used to record a sequence of conventional cardiac 2-D ultrasound images with the transducer position recorded for each image acquired to compute right ventricular volumes and ejection fraction. Specific anatomic landmarks identified by the product user are transmitted by secure internet connection to a VMS server where 3-D assembly of the right ventricle in adult patients with Pulmonary Arterial Hypertension takes place using Knowledge Based Reconstruction (KBR). The results are then returned to the VMS system for display and further consideration or evaluation by the product user.

Prescription Use __√_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OVID)

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) _____K140153_____